REMARKS/ARGUMENTS

Statement of the Substance of the Interview

The undersigned attorney thanks the examiner for extending the courtesy of conducting a telephone interview on 12 January 2009. During the interview, U.S. Patent No. 6,456,874 to Hafer et al. (hereinafter Hafer '874), U.S. Publication No. 2002/0052576 to Massengale (hereinafter Massengale), and International Publication No. WO2004/103435 to Hafer et al. (hereinafter Hafer '435) were discussed. As explained more fully in the remarks below, it is applicant's position that when the prior art is considered in its entirety, for all that it teaches, although each of the components of the device recited in claim 1 may be found in the prior art, it would not have been obvious to combine those components as set forth in amended claim 1.

Election/Restrictions

In paragraph 1 of the Office action, the restriction requirement has been made final. In response, applicant has cancelled withdrawn claims 34-49 without prejudice to the resubmission of those claims in a related application.

Drawings

In paragraph 2 of the Office action, the drawings are objected to "because reference character '34' has been used to designate both a reinforcement member and a flexible conductive member." In response, paragraph [0041] of the published application has been amended. Because the coil illustrated in the figures is one example of a reinforcement member 34, paragraph [0041] has been amended to recite that the reinforcement member 34 is "sometimes referred to herein as a flexible conductive member 34." It is believed that with that clarification, no amendment to the drawings is necessary.

Claim Rejections – 35 U.S.C. § 103

In paragraph 4 of the Office action, claims 1-9, 11-13, and 15-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Massengale in view of Hafer '874. In paragraph 5 of the Office action, claim 1, the only remaining independent claim, is discussed. The Office action provides as follows:

> Claim 1 differs from Massengale in calling for the end cap to be conductive and the device to further include a flexible conductive element attached to the end cap. Hafer teaches a catheter similar to that of Massengale, but further including a conductive end cap 72 and flexible coil 70 so that electrical stimulation can be utilized in locating the specific location of the catheter tip within the nerve (Col. 2, lines 34-41). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Massengale to include a conductive end cap and conductive flexible element as taught by Hafer so that electrical stimulation can be utilized to locate the catheter tip within the nerve.

While this argument appears reasonable on its face, it is applicant's position that this argument must fail when the prior art is considered in its entirety. More particularly, the examiner's attention is respectfully drawn to Fig. 10C of Hafer '435 which illustrates a slug type distal tip 150. The slug type distal tip 150 is discussed in conjunction with Fig. 10A, beginning on page 14 at line 27.

> The slug type distal tip 150 has three main sections of respectively increasing diameter; the cylinder 158 sized to receive the wire coil 58, the center cylinder 156 sized to receive the thermoplastic sheath 54, and the distal cylinder 157 which is of greater diameter than either the inside diameter of the thermoplastic sheath or the wire coil 58 thus avoiding being inserted too far into the catheter 54.

It is seen from Hafer '435 that although Hafer, arguably a person of at least ordinary skill in the art, having available to him all of the components recited in claim 1, nevertheless failed to combine those components as recited in amended claim 1 when constructing a stimulating catheter having a conductive end cap closing the open distal end of the flexible tube. It is respectfully submitted that, rather than speculate how a person of ordinary skill in the art might combine the various components of Massengale and Hafer '874, the embodiments of Hafer '435 are substantial evidence that a person of ordinary skill in the art would not have found the arrangement of elements recited in amended claim 1 to have been obvious.

The dome-shaped end cap recited in claim 1 is not a trivial difference over the slug type distal tip. Given the small size of these devices, see applicant's FIG. 5B, manufacturing and assembly of components is simplified using applicant's dome-shaped end cap.

During the course of the interview, the examiner brought Figs. 10-14 of Massengale to the attention of the undersigned attorney. The catheter shown in Figs. 10-14 is discussed in Massengale in paragraph [0123] as follows:

> [0123] FIGS. 10-14 illustrate an infusion catheter 320 according to one embodiment of the present invention. Catheter 320 preferably includes a flexible support 322 (FIGS. 12-14), a non-porous membrane 324, and a porous membrane 326. The membranes 324 and 326 are wrapped around the support 322 to form a plurality of axial lumens between the inner surfaces of the membranes 324 and 326 and the surface of the support 322, as described in greater detail below. The non-porous membrane 324 defines a non-infusing section 328 of the catheter 320, and preferably covers the support 322 from the proximal end thereof to a point 330, shown in FIG. 20. Similarly, the porous membrane 326 defines an infusion section 332 of catheter 20, and preferably covers the support 322 from the point 330 to the distal end of support 322. Alternatively, the catheter 320 may be configured without a non-porous membrane 324. In this configuration, the porous membrane 326 covers the entire length of the support 322, so that the entire length of the support 322 corresponds to the infusion section of the catheter 320. The infusion section can have any desired length. The proximal end of the catheter 320 may be connected to a fluid supply 334 containing a fluid 336 such as a liquid medication. The distal end of catheter 320 may include a cap 348 (FIG. 14) defining the endpoint of the axial lumens within the catheter 320.

As seen from the foregoing, the embodiment illustrated in Figs. 10-14 does not have an end cap closing the distal open end of a flexible cylindrical tube having a plurality of openings therethrough. As shown in Fig. 14, a guide wire lumen 344 extends through the center of support 322. For a guide wire 346 to extend through lumen 344 and through the end of cap 348, as seen clearly in Fig. 11, cap 348 must have an opening corresponding to guide wire lumen 344. Even when the guide wire 346 is in place, the distal end of the catheter is not closed by the cap/guide wire 346 combination due to tolerances needed to allow insertion and removal of guide wire 346. Further, the embodiment of Figs. 11-14 has a porous membrane portion 326 of variable length positioned between point 330 and cap 348. The porous membrane portion 326 is formed by wrapping the membrane 326 around support 322. As a result, the cap 348 (Fig. 14) does not close the open end of a "flexible cylindrical tube having a plurality of openings therethrough."

For the foregoing reasons, the rejection of claim 1 under 35 U.S.C. § 103(a) should be withdrawn.

Applicant at this time does not submit arguments in support of the patentability of the claims depending from claim 1, but reserves the right to do so at a later date should that become necessary.

Applicant has made a diligent effort to place the claims remaining in this application in condition for a notice of allowance. If the examiner is of the belief that the instant application is in condition for disposition other than through allowance, the examiner is respectfully requested to contact applicant's attorney at the number listed below so that additional amendments may be considered.

Respectfully submitted,

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